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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

September 10, 1998

WL-43-8

Stuart A. Millheiser, President
Pecos Pharmaceutical, Inc.
25301 Cabot Road, Suites 212/213
Laguna Hills, CA 92653

Dear Mr. Millheiser:

This letter is written in reference to your firm's marketing of the product "Glucosamine Chondroitin Double Strength." This product bears a label that reads in part, "As featured in the Best Seller *THE Arthritis Cure*." Further, on at least one occasion, this book accompanied a shipment of the product and as such the book was used as labeling.

The label statement and the use of the book as labeling cause the product, "Glucosamine Chondroitin Double Strength," to be a drug as defined in Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) because it is offered for the cure of the disease condition, arthritis.

The product is also a "new drug" (Section 201(p) of the Act) because it is not generally recognized as safe and effective for curing arthritis and it has not been approved for this purpose (Section 505 of the Act).

The drug is misbranded because the labeling, which includes both the previously-mentioned book and the product's immediate container label, is false or misleading since it suggests that the product is effective for its intended use (Section 502(a) of the Act) and because the labeling fails to bear adequate directions for use (Section 502(f)(1) of the Act).

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to make prompt orrections may result in enforcement action being initiated by the Food and Drug Administration. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office within fifteen (15) working day sof receipt of this letter describing the specific steps you have taken to correct the stated violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your response should be addressed to:

Thomas L. Sawyer
Leadership Team - Compliance
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Stuart E. Richardson, Jr.
Chief, Food and Drug Branch
714 "P" Street, Room 400
Sacramento, CA 95814